



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, DC 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 08/849,686 | 08/21/97 | DEGGERDAL | A 08269/003001 |

12M1/1119

JANIS K FRASER
FISH & RICHARDSON
225 FRANKLIN STREET
BOSTON MA 02110-2804

EXAMINER

KUNZ, G

ART UNIT

PAPER NUMBER

1211

DATE MAILED: 11/19/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

6

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8-21-97 and 10-24-97.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-18 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-18 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5 ☐ Interview Summary, PTO-413
- ☒ Notice of References Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

08/849,686
Office Action Summary

Art Unit: 1211

Claims 1 - 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification mentions only one support which can be used in the claimed process for purifying DNA. Moreover, this single support is identified exclusively by its tradename, "DynaBeads DNA Direct". This tradename is inadequate as a written description because a trademark or tradename is used to identify the source of goods, **and not the goods themselves**. A generic description of "DynaBeads DNA Direct" is required in order to make this specification properly enabling under 35 uSC 112, first paragraph.

Claims 1 - 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for purifying DNA using "DynaBeads (once a generic description is inserted into the disclosure), it does not reasonably provide enablement for any support or even any hydrophobic support because detergents typically disrupt hydrophobic interactions upon which, the examiner believes, this method is based. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The examiner requests from the applicant information about whether the DynaBeads used in the instant method is a product of the prior art. If the answer is "yes", then the examiner

Art Unit: 1211

requests marketing information about the product and how the manufacturer suggests that this product be used.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 - 12 and 14 - 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodard et al. (5,329,000).

The claims are directed to a method for purifying DNA comprising the combined use of a detergent and a solid support wherein the DNA binds to the solid support and then is eluted from said support, preferably by heating.

Woodard et al. discloses a method for purifying DNA comprising the use of a solid support (silicon tetrahydrazide) wherein the DNA binds to the solid support and can then be

Art Unit: 1211

eluted by heating (see claim 3). There is no limitation that the method of Woodard et al. cannot be used with a detergent, and traditionally such detergents are used in the lysis of cells.

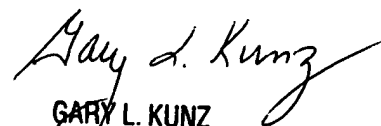
Therefore, the person of ordinary skill in the art would have found it obvious to have used the method of Woodard et al. with a cell lysate which contained a detergent. Thus, the claimed invention is prima facie obvious in the absence of clear and convincing evidence to the contrary. The limitations concerning the various detergents are simply traditional detergents used in cell lysis. The kit comprising a solid support and detergent would have also been obvious over Woodard et al. because Woodard et al. disclose a solid support for DNA purification and any detergent used in cell lysis can be employed in the Woodard et al. method.

The Cashion patent (4,379,843) is cited as an example in which nucleic acids are purified on a hydrophobic support.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kight, can be reached on (703) 308-0204. The fax phone number for this Group is (703) 308-4556.


GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200